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MAIL STOP PCT  
Attorney Docket: 26964U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: SCHMIDT  
Art Unit: Unknown  
Examiner: Unknown  
Filed: September 20, 2005  
Application No.: 10/549,631  
Title: **PROCESS FOR PREPARING CRYSTALLINE CICLESONIDE WITH  
DEFINED PARTICLE SIZE**

TRANSMITTAL LETTER

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Information Disclosure Statement;
- 2) PTO Form-1449 with 31 cited references;
- 3) Copies of 22 of the 31 cited references.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Date: December 7, 2005

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

By: 

Gary M. Nath  
Reg. No. 26,965  
Sheldon M. McGee  
Reg. No. 50,454  
Customer No. 34375

**NATH & ASSOCIATES PLLC**  
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GMN/SMM/LE (IDS)



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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

An Information Disclosure Statement is submitted herewith pursuant to 37 C.F.R. 1.97-1.98. Please note the following particulars: [NOTE: One only of items a, b, c, and d must be checked.]

[XXX] a. The enclosed statement is being filed within three months of the filing date of a national application, or within three months of the date of entry into the national stage as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing date of a first Office Action on the merits, whichever event occurs last.

[ ] b. The enclosed statement is being filed after a first action on the merits but before the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311.

The enclosed statement is accompanied by [check one]:

[ ] i. a certification in part (e) below as specified in 37 C.F.R. 1.97(e), or

[ ] ii. a check in the amount required by 37 C.F.R. 1.17(p).

[ ] c. The enclosed statement is being filed after the mailing date of a final action under 37 C.F.R. 1.113, or a notice of allowance under 37 C.F.R. 1.311, but before payment of the issue fee.

[ ] Certification report(e) below; and

[ ] a check in the amount as required by 1.17(p).

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./

[ ] d. The enclosed statement is being filed pursuant to 37 C.F.R. 1.97(i), for placement in the file.

[ ] e. Certification [Check one] [Certification is required only if box (b)(i) or box (c) is checked.]

[ ] I hereby certify that each item of information contained in the enclosed Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement,

or

[ ] I hereby certify that no item of information in the enclosed Information Disclosure Statement herewith was cited in a communication from a foreign patent office in a counterpart foreign application, or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

or

[ ] Appropriate certification is attached.

[XXX] f. If no check is enclosed and a fee is due in connection with this communication or if the check enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due in connection with this communication to Deposit Account No. 14-0112.

[XXX] g. Copies of the documents are attached herewith with a completed Form PTO-1449.

or

[ ] Copies of the documents are not attached as allowed under CFR 1.98(d)(1)(2). The earlier application is identified as:

and / or

[XXX] Copies of US Patents/Publications not attached as allowed in Official Gazette Aug. 5, 2003/ Vol. 1273, no. 1.

The Examiner is respectfully requested to cite the documents listed on the attached Form PTO-1449 in the next Office Action. In so doing, the Examiner is respectfully requested to initial in the space adjacent to the listing of each document on the Form PTO-1449, and return a copy of the initialed Form PTO-1449 with the next communication to Applicants, to confirm that these documents have been considered by the Examiner and made of record in this application.

If the Examiner has any questions or wishes to discuss this application, kindly telephone the undersigned at the below-listed number.

Date: December 7, 2005

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

By: 

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Reg. No. 26,965  
Sheldon M. McGee  
Reg. No. 50,454  
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Washington, D.C. 20005-1503  
GMN/SMM/LE (IDS.STATEMENT)

DEC 07 2005

Attorney Docket: 26964U

FORM PTO-12449

## INFORMATION DISCLOSURE CITATION

In re Application of:

SCHMIDT

Art Unit:

Unknown

Application No:

10/549,631

Filed:

September 20, 2005

Examiner:

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## U.S. PATENT DOCUMENTS

Examiner Initial		Document Number	Issue / Publication Date	Inventor	Filed
/S.B./	A1	2005/0080063 A1	04/14/2005	Schmidt	11/06/2001
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		Document Number	Publication Date	Country	Translation
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

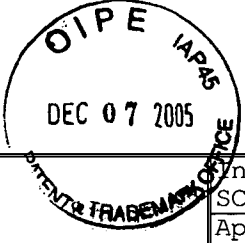
/S.B./	B5	Ruch, F, Matijevic, E., "Preparation of Micrometer Size Budesonide Particles by Precipitation", <u>Journal of Colloid and Interface Science</u> , vol. 229, pp. 207-211 (2000)
/S.B./	B6	Hem, S.L. et al., "Mechanism of Crystallization of Hydrocortisone by Ultrasonic Irradiation", <u>J. of Pharm. Sciences</u> , vol. 56, no. 2, pp. 229-233 (1967)
/S.B./	B7	Sjostrom, B. et al., "A Method for the Preparation of Submicron Particles of Sparingly Water-Soluble Drugs by Precipitation in Oil-in-Water Emulsions. II: Influence of the Emulsifier, the Solvent, and the Drug Substance", <u>J. of Pharm. Sciences</u> , vol. 82, no. 6, pp. 584-589 (1993)

Examiner

Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP ' 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.B./


 DEC 07 2005

FORM PTO-1449

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## U.S. PATENT DOCUMENTS

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/S.B./	B8	4,605,517	08/12/1986	Riley et al.	10/11/1984
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## FOREIGN PATENT DOCUMENTS

		Document Number	Publication Date	Country	Translation
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/S.B./	D4	00/38811 A1	07/06/2000	WIPO	N/A

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

Examiner /Sean Basquill/ (04/22/2009)	Date Considered 04/22/2009
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